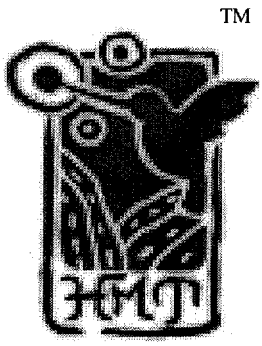
V. 510(K) SUMMARY

DEC 1 1 2001

510(K) Summary
As required by section 807.92(c)



Hummingbird Medical Technology L.L.C.
1427 Greenbriar Dr.
Allen, TX 75013
Phone: 214-284-5433
Fax: 214-495-8888
Geoffrey Hsu (General Manager)
July 4th 2001

Device Name: *H.M.T. Acupuncture Needle, Signal Use*
Common Device Name: *Acupuncture Needle, Signal Use*
Product Code: *MQX*
Medical Specialty: *General Hospital*
Device Class: *II*

Hummingbird brand acupuncture needles are defined as prescription devices intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the States.
FDA had issued 510(K)s to 47 different signal use acupuncture needles brand and them have been used for general practice of acupuncture in the United States since 1996. We had searched Federal Consumer Information Center web site http://www.pueblo.gsa.gov ***and U.S. Consumer Product Safety Commission web site*** http://www.cpsc.gov ***and found no serious or life threatening accidents involving acupuncture needles.***
Hummingbird brand acupuncture needles are sterile, single use only. The design, material used, sterility and biocompatibility of this acupuncture needle meet the general specifications and criteria for an single use acupuncture needle and is effective for the practice of acupuncture.
In conclusion, based on the information provided with this 510(K) Notification, the Hummingbird acupuncture needles meet the criteria for 510(k) acceptance. The Hummingbird acupuncture needles is equivalent to other acupuncture needles which are currently being sold through interstate commerce.

7-29-01

Geoffrey M. C. Hsu (General Manager) *Date*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 1 2001

Mr. Geoffrey Hsu
Hummingbird Medical Technology, L.L.C
1427 Greenbriar Drive
Allen, Texas 75013

Re: K012501
Trade/Device Name: H.M.T Acupuncture Needle
Regulation Number: 880.5580
Regulation Name: Acupuncture Needle, Single Use
Regulatory Class: II
Product Code: MQX
Dated: October 12, 2001
Received: October 19, 2001

Dear Mr. Hsu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

IV. STATEMENT OF INDICATIONS FOR USE

Hummingbird brand acupuncture needles will be used for "Intended to pierce the skin in the practice of acupuncture by qualified practitioners of acupuncture as determined by the states."

Vicki Hubbard for Pat Cucuzzi 12/12/01
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012501